

LOS ANGELES COUNTY DEPARTMENT OF PUBLIC HEALTH TUBERCULOSIS CONTROL PROGRAM

APPLICATION FOR REVIEW OF RESEARCH PROPOSALS

All requests to conduct research with the Los Angeles County Department of Public Health (DPH) Tuberculosis Control Program (TBC) must be approved by the TBC Research Committee and follow the format outlined in this document. Proposals must be submitted by the review dates below to be considered. Note that research will not be reviewed in the intervening periods so please plan your submission in accordance with your intended start dates. You will be notified in writing of the Committee decision.

Approval from the TBC Research Committee <u>DOES NOT</u> guarantee approval of your research proposal by the Los Angeles County Department of Public Health Institutional Review Board.

SUBMISSION DATE	COMMITTEE REVIEW DATE	NOTIFICATION LETTER DATE	
BY JANUARY 1	NO LATER THAN FEBRUARY 28	APRIL 15	
BY MARCH 1	NO LATER THAN APRIL 30	JUNE 15	
BY MAY 1	NO LATER THAN JUNE 30	AUGUST 15	
BY JULY 1	NO LATER THAN AUGUST 31	OCTOBER 15	
BY SEPTEMBER 1	NO LATER THAN OCTOBER 31	DECEMBER 15	
BY NOVEMBER 1	NO LATER THAN DECEMBER 31	FEBRUARY 15	

	Title of research proposal:	Date Received by TBC:
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PRINCIPAL RESEARCHER (ATTACH CURRICULUM VITAE WITH APPLICATION)

Name:	
Organization:	
Address:	
Telephone:	
Email:	

COUNTY OF LOS ANGELES DEPARTMENT OF PUBLIC HEALTH TUBERCULOSIS CONTROL PROGRAM

REQUIRED FORMAT FOR RESEARCH PROPOSALS

(Please attach separate Microsoft Word document to Page 1 of this document)

1. Description of Research Proposal

- A. Brief Summary of Literature Review
- B. Summary Statement of Problem
- C. Research Questions or Specific Objectives
- D. Research Hypothesis
- E. Study Design and Methodolgy

2. Detailed Description of Research Procedures

- A. Materials/Subjects Needed to Conduct the Research and Description of Sampling Procedure
- B. Approximate Dates to Begin and End Data Collection
- C. Instructions, Instruments, or Apparatus to be Used (Describe and Attach Copies)
- D. Technology to be Used (Infrastructure, Networking, Hardware, Software, etc.)
- E. Specific Activities and Names of Person(s) Responsible for Carrying Out Each Activity
- F. Description of Project Funding

3. Results of Research

- A. Benefits and Risks to the Subjects if Any
- B. Benefits to the County of Los Angeles Department of Public Health
- C. Use of Information Gained From the Research
- D. How and to Whom the Data Will be Reported
- E. Statement of Agreement to Share Final Research Results with TBC

HOW TO APPLY TO CONDUCT RESEARCH USING DPH TBC DATA/SUBJECTS

Please email your proposal to the Chair of the TBC Research Committee. You must follow the above-referenced format for research proposals and include copies of surveys, interview questions, data collection instruments, etc. The Research Committee will review the proposal based on the following criteria:

- 1. There must be minimal impact on DPH/TBC staff time.
- 2. The research should be beneficial to TBC. Potential risks to TBC data/subjects must be minimal.
- 3. Research conducted primarily to add to the general body of literature without significant benefit to TBC may be considered. However, such proposals will be considered low priority and be treated as such.
- 4. All research must be of high quality and aligned with TBC Strategic Goals.
- 5. All research must be legal, ethical, and in line with DPH and TBC policy. The privacy of research participants must be protected at all times.
- 6. Researchers must be qualified to conduct research. The design and implementation of the proposal must be well-constructed and acceptable to TBC.
- 7. DPH must approve any potential costs incurred to DPH prior to any conducting any research.

All proposals will be reviewed by the TBC Research Committee. Committee members may seek input from potential stakeholders, professionals or academics who may have specialized knowledge of the proposed research or specific aspects of the proposed research such as epidemiologists, nurses, physicians, biostaticians, etc. Such input may be used to make decisions regarding research approval. You will be notified in writing if denied. If your proposal is denied, you may request reconsideration of your proposal if you can provide additional pertinent information and/or clarify information you feel may have been misunderstood during the review.

If your proposal is approved you will be asked to sign a Statement of Agreement stating the responsibilities of both DPH (Community Health Services), TBC and you or your organization. Full disclosure must be given to subjects to ensure informed consent. Subjects must give written informed consent.

LEGAL AND ETHICAL RISKS AND OBLIGATIONS

The research must conform to federal regulations, DPH policy and sound medical research practice that ensures negligible risks for those involved and research subject privacy and protection rights. To this end, the researcher(s) must have the qualifications necessary for conducting medical research. With some exceptions, TBC approval will be granted until specified data collection has concluded or for a maximum of two years from the date of the approval letter. For any research extending beyond two years, the researcher must submit an annual progress report along with a request for extension.

If the research involves human subjects, copies of all approved and completed informed consent forms must be stored by the researcher for possible TBC review. Confidentiality of health records and subject information must be observed. Data with subject identifiers must not be reported or presented. In addition to maintaining complete anonymity, all identifying data must be destroyed upon completion of analysis and the final report. Approval to conduct research may be withdrawn if the researcher is found to be non-compliant with established DPH policies and procedures. If approval is terminated, all research and accompanying activities involving DPH, TBC and the researcher will cease. Note that DPH (Community Health Services) and/or TBC will not compile or collect data for external research unless noted otherwise. All research approval or denial is determined by the TBC Research Committee in accordance with the Director of TBC. Also note that denial letters may or may not indicate reasons for denial or recommendations for improvement. All research approvals or denials are made on the merits of the information contained in the application. Therefore, the Research Committee may or may not contact the researcher if questions arise. The application, following the required format, is the source of information on which all decisions are made.

Upon conclusion of the research, a copy of the final report will be submitted at no charge to the Chair of the TBC Research Committee. If a more formal report is to be released (dissertation, thesis, book, journal article, etc.), the author will provide TBC a formal copy at no charge. The researcher further agrees to release this report for use by TBC without renumeration and to give TBC authorial credit in the final, published report.

In addition, all data and databases are to remain secure at all times. If DPH or TBC specifically supplies existing data or databases, then upon completion of the originally approved research, the existing data will be returned to DPH and/or TBC with no copies remaining and access to databases will be terminated. In the event a researcher wishes to publish using existing data via analyses or methods not originally produced or approved within the study, DPH and TBC reserve the right to disallow access to data for further analyses and reporting.

ASSU	IRA	NC	ES:
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The TBC Research Committee seeks to conduct relevant research in collaboration with other TB control programs, public health laboratories, academic institutions, hospitals, or other organizations to further improve the diagnosis, clinical management, or prevention of TB infection and disease in Los Angeles County. The proposed study shall conform to applicable federal and state regulations in addition to Los Angeles County Department of Public Health policies. I understand that sound educational research practice ensures neglible risks for those involved including healthcare information privacy and protection rights. Further, I assure that the research performed will not significantly differ from the research proposed above and I understand that any changes to any aspect of the research proposal will require prior written notification to and approval by the TBCP research committee and applicable IRB committee(s). I understand that the privilege of conducting future research studies with the Los Angeles Department of Public Health Tuberculosis Control Program is conditioned upon the fullfillment of such obligations.

Applicant signature:		
Date:		

QUESTIONS ABOUT RESEARCH REVIEW PROCEDURES OR THE ACCEPTABILITY OF RESEARCH PRACTICES SHOULD BE REFERRED TO:

DR. RASHMI JAN SINGH M.D. Chair, TBC Research Committee Los Angeles County Department of Public Health Tuberculosis Control Program 2615 S. Grand Avenue, Rm. 507 Los Angeles, CA 90007

EMAIL: rasingh@ph.lacounty.gov

PHONE: (213) 744-6254